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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/017,715	02/03/1998	HONGJUN JI	1488.0810003	8739

22195 7590 10/27/2004

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 10/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/017,715	JI ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-42,44-47,50,51,53 and 57-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *57-70* is/are allowed.

6)☐ Claim(s) *16-42,44-47,50,51,53 and 71-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. After review and reconsideration, the finality of the Office action of Paper No. 30, mailed November 4, 2002, is withdrawn.

2. Claims 44, 45, 57, 71, 72, 76 and 77 have been amended according to the response of January 3, 2003. The amendment filed August 9, 2002 requested an amendment to claim 48, however, claim 48 was canceled in the amendment filed August 10, 2001. Claims 16-42, 44-47, 50, 51, 53 and 57-77 are pending and under consideration.

3. The amendment filed August 9, 2002 changed the effective filing date of the instant application from June 30, 1995, based on 60/000,602, to February 3, 1997. Accordingly the following rejections are applied.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 16-42, 44-47, 50, 51, 53, 71 and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by Moore et al (US 6,054,289, priority to August 30, 1996).

Claim 16 is drawn to an isolated polynucleotide comprising a nucleic acid encoding amino acids 2-127 of SEQ ID NO:2. Claim 17 embodies the polynucleotide of claim 16, comprising nucleotides 15-392 of SEQ ID NO:1 Claim 18 embodies the polynucleotide of claim 16 comprising a nucleic acid encoding amino acids 1-127 of SEQ ID NO:2. Claim 19 embodies the polynucleotide of claim 18, comprising nucleotides 12-392 of SEQ ID NO:1. Claims 20 and 21 embody the polynucleotide of claim 16 which is DNA and RNA respectively. Claim 22 embodies the polynucleotide of claim 16 further comprising a heterologous polynucleotide. Claim 23 embodies the polynucleotide of claim 22 wherein the heterologous polynucleotide encodes a heterologous polypeptide. Claim 30 is drawn to a composition comprising the isolated polynucleotide of claim 16 and a pharmaceutically acceptable carrier. Claim 31 is drawn to an isolated polynucleotide comprising the nucleic acid sequence encoded by the cDNA clone of ATCC. Claims 32 and 33 embody the polynucleotide of claim 31 which is DNA and RNA respectively. Claim 34 embodies the polynucleotide of claim 31 further comprising a heterologous polynucleotide. Claim 35 embodies the polynucleotide of claim 34 wherein the heterologous polynucleotide encodes a polypeptide. Claim 42 is drawn to a composition comprising the polynucleotide of claim 31 and a pharmaceutically acceptable carrier

Claims 25, 37 and 51 are drawn to a vector comprising the polynucleotide of claims 16, 31 and 44, respectively. Claims 26 and 38 embody the polynucleotides of claim 25 and 37, respectively, wherein the vector is operably associated with a heterologous regulatory sequence.

Claims 27, 39 and 52 are drawn to a host cell comprising the isolated polynucleotides of claims 16, 31 and 41, respectively. Claims 28 and 40 embody the polynucleotide of claims 27 and 39, respectively, wherein said polynucleotide is operably associated with a heterologous regulatory sequence.

Claims 24, 36 and 50 are drawn to a method of producing a vector comprising inserting the polynucleotide of claims 16, 31 and 44, respectively, into a vector.

Claims 29 and 41 are drawn to a method of producing a polypeptide comprising culturing the host cells of claims 28 and 40, respectively, under conditions wherein the polypeptide is expressed and recovering said polypeptide.

Claim 44 is drawn in part to the complement of an isolated polynucleotide fragment consisting of 100 contiguous nucleotides of SEQ ID NO:1. Claim 45 embodies the complement of the polynucleotide fragment of complement of claim 44 consisting of 250 contiguous nucleotides of SEQ ID NO:1. Claims 46 and 47 embody the fragment of claims 44 which are DNA and RNA, respectively.

Claim 71 embodies an isolated nucleic acid at least 95% or more identical to amino acids 1-127 of SEQ ID NO:2 or 95% identical to the amino acid sequence encoded by the cDNA in ATCC Deposit No. 97856, wherein said polypeptide is over expressed in breast cancer. Claim 76 is drawn in part to an isolated polynucleotide comprising a nucleic acid encoding an amino acid sequence 95% or more identical to amino acids 1-127 of SEQ ID NO:2 or the amino acid sequence encoded by the cDNA clone continued in the ATCC Deposit 97856, wherein said polynucleotide is over expressed in breast cancer.

Moore (US 6,054,289) disclose the polynucleotide sequence in the HBGBA67X Clone which comprises the nucleic acid sequence of SEQ ID NO:1 and encodes the polypeptide of SEQ ID NO:12 (column 2, lines 21-26). SEQ ID NO:12 of Moore is identical to the instant SEQ ID NO:2. Moore discloses that the HBGBA67X is an amyloid-like protein expressed in breast (column 26, Tables 1 and 2). The disclosure of Moor anticipated claims 44-47 because the HBGBA67X Clone comprises a complementary strand which would be the complement of the claimed fragments, because claims 44-47 do not specify that the complements be shorter than SEQ ID NO:1. The HBGBA67X Clone comprises a vector and heterologous regulatory sequences for expression of SEQ ID NO:1. Moor discloses a method for producing a recombinant protein comprising a bacaloviral expression system (column 21, Example 2) using Sf9 insect cells as host cells (column 22, lines 41-42). Moor also discloses COS cells as host cells (column 23, Example 3). Although Moore does not specifically disclose that the HBGBA67X Clone would express a heterologous polypeptide such as beta-lactamase to facilitate expression of the protein in a bacterial system (column 21, lines 10-11). SEQ ID NO:1 of Moore anticipates claims 71 and 76 because SEQ ID NO:1 of Moore would be 100% identical to the nucleic acids encoding the amino acid sequence encoded by the cDNA clone continued in the ATCC Deposit 97856.

6. Claims 71-77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polyncuetides comprising nucleotides 15-392 of SEQ ID NO:1, isolated nucleic acids encoding SEQ ID NO:2, does not reasonably provide enablement for isolated nucleic acids which are 95% identical to nucleotides 15-392 of SEQ ID NO:1, isolated nucletic acids having 95% sequence identity to a polynucleotide encoding SEQ ID NO:2 or the cDNA clone of ATCC 97856, isolated nucleic acids encoding an amino acid sequence having 95% identity to SEQ ID NO:2 or the amino acid sequence encoded by the cDNA clone of ATCC 97856, or isolated nucleic acids comprising a nucleic acid sequence having one to thirty conservative amino acid substitutions in SEQ ID NO:2 or the amino acid sequence encoded by the cDNA clone of ATCC 97856, wherein said variant nucleic acids and amino acid sequences are over expressed in breast cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims..

Claim 71 is drawn to an isolated nucleic acid at least 95% or more identical to amino acids 1-127 or 2-127 of SEQ ID NO:2 or 95% identical to the amino acid sequence encoded by the cDNA in ATCC Deposit No. 97856, wherein said polypeptide is over expressed in breast cancer.

Claim 72 is drawn to an isolated polynucleotide comprising a nucleic acid encodings an amino acid sequence, wherein except for one to thirty consecutive amino acids substitutions, said amino acid sequence is amino acids 1-127 of SEQ ID NO:2 or the amino acid sequence encoded by the cDNA clone continued in the ATCC Deposit 97856, wherein said polynucleotide is over expressed in breast cancer. Claims 73-75 embody the isolated nucleic acid of claims 72, 73 and 74, wherein the substitutions are not more than 10, 5 or 3, respectively.

Claim 76 is drawn to an isolated polynucleotide comprising a nucleic acid encoding an amino acid sequence 95% or more identical to amino acids 1-127 or 2-127 of SEQ ID NO:2 or the amino acid sequence encoded by the cDNA clone continued in the ATCC Deposit 97856, wherein said polynucleotide is over expressed in breast cancer.

The instant claims are drawn to variant nucleic acid sequences or polynucleotide encoding variants of SEQ ID NO:2, wherein said variant polynucleotide are over expressed in breast cancer. The first paragraph of 35 U.S.C. 112, requires that the specification be enabling

for making and using a claimed product without undue experimentation. In order to fulfill the specific embodiments of the instant claims, it would be necessary to first isolate the variant polynucleotides from breast cancer tissue. Once the sequence of the variant polynucleotides were determined, one of skill in the art could then proceed with making the polynucleotides. The specification has not provided any evidence that said variants having 95% identity to SEQ ID NO:1, or variants encoding an amino acid sequence having 95% identity to SEQ ID NO:2, or variants encoding SEQ ID NO:2, with the exception of one to thirty conservative amino acid substitutions within SEQ ID NO:2 exist within breast cancer tissue. It is noted that a variant having 30 conservative amino acid substitutions within SEQ ID NO:2 would have only 76% sequence identity to SEQ ID NO:2. Without any evidence that said variants exist as over expressed polynucleotides or polypeptides in breast cancer tissue, one of skill in then art would be subject to undue experimentation, without reasonable expectation of success in order to isolate the variants within the scope of the broadly claimed invention.

7. All other rejections and objections as set forth in the previous Office action are withdrawn.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
10/25/2004

Karen A. Canella

KAREN A. CANELLA PH.D
PRIMARY EXAMINER